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Dkt. 2259/65532-A-PCT-US/JPW/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Lawrence G. Lum et al.

Serial No. : 10/553,853

Examiner: Not Yet Known

Intl.

Filing Date: April 23, 2003

Art Unit: Not Yet Known

For : COMPOSITIONS AND METHODS FOR STEM CELL DELIVERY

1185 Avenue of the Americas  
New York, New York 10036  
May 29, 2007

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A). Copies of references 3-22 are attached hereto as Exhibits 1-20, respectively.

1. U.S. Patent No. 5,762,930, issued June 9, 1998, to Fanger et al.;
2. U.S. Patent No. 6,096,311, issued August 1, 2000, to Fanger et al.;
3. PCT International Search Report issued November 14, 2003 in connection with PCT International Application No.

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PCT/US2003/012679, filed April 23, 2003, PCT Publication No.  
WO/2003/091398 A3, published November 6, 2003, on behalf of  
Roger Williams Hospital et al. (Exhibit 1);

4. Communication Pursuant to Article 157(2)(a) EPC including Supplementary European Search Report issued February 15, 2007 in connection with European Patent Application No. EP 03 73 1044, filed April 23, 2003 on behalf of Roger Williams Hospital et al. (Exhibit 2);
5. European Application No. 88 108 793.6, filed on June 6, 1988, European Publication No. 0 294 703, published December 14, 1988, on behalf of Dana-Farber Cancer Institute, Inc. (Exhibit 3);
6. Almeida-Porada, G. et al. (1999) "Transplantation of Human Neuronal Stem Cells into Fetal Sheep Give Rise to Hematopoietic Cells In Vivo," *Blood* 94: 129a (abstract #567) (Exhibit 4);
7. Bjornson, C. et al. (1999) "Turning Brain Into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells In Vivo," *Science* 283:534-537 (Exhibit 5);
8. Ferrari, G. et al. (1998) "Muscle Regeneration by Bone Marrow-Derived Myogenic Progenitors," *Science* 279:1528-1530 (Exhibit 6);

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9. Gussoni, E. et al. (1999) "Dystrophin Expression in the *mdx* Mouse Restored by Stem Cell Transplantation," *Nature* 401:390-394 (Exhibit 7);
10. Jackson, K. A. et al. (1999) "Hematopoietic Potential of Stem Cells Isolated from Murine Skeletal Muscle," *Proc. Natl. Acad. Sci. U.S.A.* 96:14482-14486 (Exhibit 8);
11. Kawada, H. et al. (2001) "Bone Marrow Origin of Hematopoietic Progenitors and Stem Cells in Murine Muscle," *Blood* 98:2008-2013 (Exhibit 9);
12. Krause, D. S. et al. (2001) "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," *Cell* 105:369-377 (Exhibit 10);
13. Lagasse, E. et al. (2000) "Purified Hematopoietic Stem Cells can Differentiate into Hepatocytes *in vivo*," *Nat. Med.* 6:1229-1234 (Exhibit 11);
14. Lum, L. et al. (2001) "Activated T-Cell and Bispecific Antibody Immunotherapy For High-Risk Breast Cancer," *Acta Haematol.* 105:130-136 (Exhibit 12);
15. Orlic, D. (2001) "Hematopoietic Cells Regenerate Infarcted Myocardium," *Exp. Hematol.* (Suppl) 29:4 (abstract #10) (Exhibit 13);

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16. Orlic, D. et al. (2000) "Transplanted Hematopoietic Stem Cells Repair Myocardial Infarcts," *Blood* 96:221a (abstract #943) (Exhibit 14);
17. Petersen, B. E. et al. (1999) "Bone Marrow as a Potential Source of Hepatic Oval Cells", *Science* 284:1168-1170 (Exhibit 15);
18. Raso, V. et al. (1997) "Intracellular Targeting With Low pH-triggered Bispecific Antibodies," *Journ. Biol. Chem.* 272:27623-27628 (Exhibit 16);
19. Riedle, S. et al. (1998) "In Vivo Activation and Expansion of T Cells By a Bi-Specific Antibody Abolishes Metastasis Formation of Human Melanoma Cells in SCID Mice," *Int. J. Cancer* 75:908-918 (Exhibit 17);
20. Theise, N. D. et al. (2000) "Derivation of Hepatocytes from Bone Marrow Cells in Mice after Radiation-induced Myeloblation," *Hepatology* 31:235-240 (Exhibit 18);
21. Valtz, N. L. et al. (1991) "An Embryonic Origin for Medulloblastoma," *New Biologist* 3:364-371 (Exhibit 19); and
22. Wakitani, S. et al. (1995) "Myogenic Cells Derived from Rat Bone Marrow Mesenchymal Stem Cells Exposed to 5-Azacytidine," *Muscle Nerve* 18:1417-1426 (Exhibit 20).

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An International Search Report was issued on November 14, 2003 in connection with PCT International Application No. PCT/US2003/012679, filed April 23, 2003, of which the subject application is a \$371 national stage application. A copy of the Search Report is attached hereto as **Exhibit 1**. Above-listed references 1, 2, 5 and 18 were cited in the International Search Report.

European Patent Application No. EP 03 73 1044, filed April 23, 2003, is a related regional stage application claiming priority of PCT International Application No. PCT/US2003/012679. A Supplementary European Search Report was issued on February 15, 2007 in connection with European Patent Application No. EP 03 73 1044. A copy of the Supplementary European Search Report is attached hereto as **Exhibit 2**. Above-listed references 14 and 19 were cited in the Supplementary European Search Report.

Above-listed references 1 and 2 are U.S. patents. Accordingly, pursuant to 37 C.F.R. §1.98(a)(ii) copies of these patents are not required to be provided to the United States Patent and Trademark Office.

Applicants request that the Examiner review the references listed above and make them of record in the subject application.

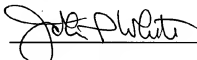
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned

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attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450	
 John P. White Reg. No. 28,678	5/29/07 Date

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<b>Application Number</b>	10/553,853
<b>Intl. Filing Date</b>	April 23, 2003
<b>First Named Inventor</b>	Lawrence G. Lum
<b>Art Unit</b>	Not Yet Known
<b>Examiner Name</b>	Not Yet Known
<b>Attorney Docket No.</b>	2259/65532-A-PCT-US/JPW/MVM

## U.S. PATENT DOCUMENTS

[illegible]

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Number <sup>2</sup> Kind Code <sup>3</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
	5	EP 0 294 703	12-14-1988	Dana-Farber Cancer Institute, Inc.	

DATE CONSIDERED \_\_\_\_\_

\* **EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds of Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MB/

Exhibit A

<b>Form PTO-1449</b> <b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>  <b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)	Application Number	10/553,853
	Int'l. Filing Date	April 23, 2003
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	Art Unit	Not Yet Known
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	Attorney Docket No.	2259/65532-A-PCT-US/JPW/MVM

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	3	PCT International Search Report issued November 14, 2003 in connection with PCT International Application No. PCT/US2003/012679, filed April 23, 2003, PCT Publication No. WO/2003/091398 A3, published November 6, 2003, on behalf of Roger Williams Hospital et al.	
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	8	Ferrari, G. et al. (1998) "Muscle Regeneration by Bone Marrow-Derived Myogenic Progenitors," <i>Science</i> 279:1528-1530	
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	10	Jackson, K.A. et al. (1999) "Hematopoietic Potential of Stem Cells Isolated from Murine Skeletal Muscle," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96:14482-14486	
	11	Kawada, H. et al. (2001) "Bone Marrow Origin of Hematopoietic Progenitors and Stem Cells in Murine Muscle," <i>Blood</i> 98:2008-2013	
	12	Krause, D.S. et al. (2001) "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," <i>Cell</i> 105:369-377	
	13	Lagasse, E. et al. (2000) "Purified Hematopoietic Stem Cells can Differentiate into Hepatocytes in vivo", <i>Nat. Med.</i> 6:1229-1234	

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	14	Lum, L. et al. (2001) "Activated T-Cell and Bispecific Antibody Immunotherapy For High-Risk Breast Cancer," <i>Acta Haematol.</i> 105:130-136	
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EXAMINER SIGNATURE	/Michail Belyavsky/	DATE CONSIDERED	(07/22/2006)
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